MINUTES OF THE DRUG FORMULARY COMMISSION

Meeting of October 15, 2015

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

DRUG FORMULARY COMMISSION
MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH
Henry I. Bowditch Public Health Council Room, 2nd Floor
250 Washington Street, Boston MA

Docket: Thursday, October 15, 2015 9:00 AM

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1. **ROUTINE ITEMS:**
    a. Welcome and Opening Remarks
    b. Approval of the Minutes **(Vote)**
2. **REVIEW OF OCTOBER 1, 2015 MEETING:**
    a. Feedback from Invited Panelists
3. **DISCUSSION OF EVALUATION CRITERIA:**
    a. Heightened Public Health Risk Criteria
        i. Drug Groups **(Vote)**
    b. Therapeutically Equivalent Substitution Criteria

Drug Formulary Commission

Presented below is a summary of the meeting, including time-keeping, attendance and votes cast.

Date of Meeting: Thursday, October 15, 2015
Beginning Time: 9:04 AM
Ending Time: 11:52 AM
Attendance and Summary of Votes:

Board Member	Attended	Minutes	Heightened Public Health Risk Criteria: Drug Groups
Dr. Dan Alford	Absent	Absent	Absent
Dr. Douglas Brandoff	Yes	Yes	Yes
Cheryl Campbell	Absent	Absent	Absent
Ray Campbell III	Yes	Yes	Yes
Dr. Daniel Carr	Yes	Not Voting	Yes
Joanne Doyle-Petrongolo	Yes	Yes	Yes
Stephen Feldman	Yes	Yes	Yes
Dr. Kenneth Freedman	Yes	Not Voting	Yes
Dr. Paul Jeffrey	Yes- arrived at 9:27 AM	Not Voting	Yes
Virginia Lemay	Yes	Yes	Yes
Eric Sheehan	Yes	Not Voting	Not Voting
Cindy Steinberg	Yes	Yes	Yes
Dr. Jeffrey Supko	Absent	Absent	Absent
Dr. Theoharis Theoharides	Absent	Absent	Absent
Tammy Thomas	Yes	Yes	Yes
Dr. Alexander Walker	Absent	Absent	Absent
Summary	**11 Members attended**	**7 Approved with votes**	**10 Approved with votes**

1. PROCEEDINGS

A regular meeting of the Drug Formulary Commission (M.G.L. Ch. 17, § 13) was held on Thursday, October 15, 2015 at the Massachusetts Department of Public Health, 250 Washington Street, Henry I. Bowditch Public Health Council Room, 2nd Floor, Boston, Massachusetts 02108.

Members present were: Department of Public Health Interim Director of the Bureau of Health Care Safety and Quality, Eric Sheehan (Chair), Dr. Douglas Brandoff, Dr. Daniel Carr, Mr. Ray Campbell III, Dr. Joanne Doyle-Petrongolo, Mr. Stephen Feldman, Dr. Kenneth Freedman, Dr. Paul Jeffrey, Dr. Virginia Lemay, Ms. Cindy Steinberg, and Ms. Tammy Thomas.

Absent members were: Dr. Dan Alford, Ms. Cheryl Campbell, Dr. Jeffery Supko, Dr. Theoharis Theoharides, and Dr. Alexander Walker.

Also in attendance were the following staff from the Department of Public Health: Suzanne Cray, Director of the Office of Health Care Integration at the Bureau of Health Care Safety and Quality; Jonathan Mundy, Director of the Office of Prescription Monitoring and Drug Control at the Bureau of Health Care Safety and Quality; Lauren Nelson, Director of Policy and Quality Improvement at the Bureau of Health Care Safety and Quality; and David Dunn, Associate Executive Director of the Board of Registration in Pharmacy.

Interim Director Sheehan called the meeting to order at 9:04 AM. He reminded the members that the meeting was being recorded. Interim Director Sheehan thanked the Commission members for attending the first three meetings and assessed the current status of the Commission.

He began by talking about the last meeting on October 1. He stated during this meeting, we heard extensive feedback from a diverse group of experts related to their experience with drug formularies. We also heard helpful comments on their recommendations as to how the Commission should evaluate potential therapeutically equivalent substitutes based on the four factors outlined in Chapter 258. He stated as a reminder, the four factors are:

- The efficacy of the drug;
- The effectiveness of its abuse deterrent properties;
- The accessibility of the drug; and
- The cost effectiveness.

Interim Director Sheehan stated that at today's meeting, we will discuss the comments and written testimony received from the experts and other stakeholders. We will consider this feedback as we continue development of the evaluation and review criteria that the Commission will use to complete the components of its work.

Interim Director Sheehan reviewed the current status of the Commission's work in the Evaluation and Review Process. He stated the Commission's task is to develop a formulary that consists of three components.

Component 1: The Commission will determine which groups of drugs should be designated as having a heightened public health risk.

Component 2: The Commission will determine which drugs should be identified as therapeutically equivalent substitutes to the drugs that have a heightened public health risk.

Component 3: The Commission will complete a crosswalk and develop a formulary of therapeutically equivalent substitutes for drugs determined to be having a heightened public health risk.

He added following completion of these components, the Commission will have a draft formulary. He stated we have spent time understanding the process to develop the drug formulary and the timeline for achieving our goals. Our last meeting allowed us to hear outside perspectives as we make process on our work plan for developing the formulary.

Considering the work and discussion to date, our next key task is to establish the criteria in which the Commission will determine if a drug should be placed on the formulary as having a heightened public health risk or as a therapeutically equivalent substitute. He stated our goal for today's meeting is to make significant progress on the creation of the criteria, potentially even voting to finalize aspects of it.

By meeting this goal, we will be in the position to start reviewing the application of the final criteria to specific drugs at our November meetings. This will keep us on target to evaluate specific drugs over the winter months and have a draft formulary completed in the winter.

Interim Director Sheehan asked if there were any changes to minutes from the October 1st meeting, after which Dr. Doyle-Petrongolo had a comment to add her statement made at the meeting to include the formulary as part of the electronic health record.

Interim Director Sheehan then asked if there was a motion to vote to approve the minutes with this addition, and Ms. Steinberg motioned to approve the minutes, and Mr. Feldman seconded the motion for approval of the minutes. Interim Director Sheehan declared the minutes approved after a unanimous vote. Dr. Jeffery was not present for the discussion or vote of this matter.

2. REVIEW OF OCTOBER 1 MEETING

Interim Director Sheehan reminded Commission members that, the goal of the October 1st meeting was to make sure that the Commission has the most relevant, timely and beneficial information available and get expert feedback to consider as part of the work to develop the formulary. He added that we heard from 11 experts from diverse fields and received written testimony from 7 individuals, including 4 that gave remarks.

He mentioned that all testimony was provided to Commission members in advance so that we could review and discuss the major points that were raised. Interim Director Sheehan specifically addressed testimony that Commission members heard during the October 1st meeting regarding the need for the Commission to use chemical versus therapeutically equivalent drug products as substitutes to drugs that have been determined to have a heightened public health risk. Interim Director Sheehan reminded Commission members that this topic was discussed at the September 8th meeting and noted that it was the Department's responsibility to review and interpret the statute. From this review, the intent was for a formulary of therapeutic substitutes to be determined.

Next, Interim Director Sheehan introduced David Dunn to facilitate a discussion of the observations from the October 1st meeting.

Associate Executive Director Dunn conducted a presentation of the key observations from the meeting. He noted that some of the points stressed by testifiers, such prescriber education, and the prior authorization process, may fall outside of the scope of the Drug Formulary Commission but is still relevant feedback to consider as we take a holistic view of the work before the Commission.

Mr. Feldman stated he though the panel meeting was valuable but believes that many testifiers thought the formulary was mandatory and not voluntary for prescribers to utilize. Interim Director Sheehan provided clarification that the formulary is just one aspect of the tools available to prescribers but is not mandated. Even after the Commission votes on a draft formulary, it will be a fluid document and will change. It also needs to go through the regulation review and promulgation process, including presentation to the Public Health Council.

Ms. Steinberg asked if the formulary was still flexible and not mandatory if it needs to be adopted by regulation. Interim Director Sheehan stated that it was as it was a tool to assist prescribers. We are not here to dictate the patient-prescriber relationship.

Dr. Paul Jeffrey arrived at 9:26 AM.

Associate Executive Director Dunn added that if a practitioner wants to use the substitution recommended by the formulary, he would have to prescribe it. Drug and strength changes must only made by the practitioner based on federal law. He clarified that a pharmacist can make a generic substitution but not a therapeutic substitution of controlled substances in Schedule II.

Dr. Freedman brought up Mr. Feldman's previous point, stating that it seemed like some testifiers believed it would be mandatory formulary and worried about delay in therapy providing the prescription. This should not be an issue if the formulary is voluntary because the pharmacist would not need to seek out the prescriber if substituting. He added as an example that there are 4 different formulations of buprenorphine and many managed care companies have a preferred formulation that can cause delay if patient not prescribed one of the preferred medications. It needs to be put in an introduction to the formulary that it is voluntary.

Dr. Freedman also noted that the testifiers felt that it was important for there to be recommendations of safe prescribing. Even if it is not within the jurisdiction of this Commission, it is an important issue and maybe we can share these recommendations with an appropriate body. Interim Director Sheehan noted that it is not within the Commission's jurisdiction but it is an issue that is being considered by other areas within the Department. He noted that it may be possible to have the Department's Bureau of Substance Abuse Services (BSAS) present on their efforts.

Dr. Brandoff stated he understands that the Commission needs to stay within its authority but we need to think about the impact of the formulary and other recommendations even if they are not mandatory.

Dr. Doyle-Petrongolo indicated that there are still prescribers that do not know what the PMP is or are not using it to the fullest extent. Interim Director Sheehan responded that the new MA Online PMP is a top initiative that is still in the procurement phase but we will give a full update to the Commission once we are able.

Dr. Carr stated we have an action item of needing a clear statement that education is important. Governor Baker and Commissioner Bharel are put together a panel of the four deans of Massachusetts' medical schools on this issue. He also stated that we need to clarify that chemically equivalent can be interpreted as therapeutically equivalent as having the same course of action in a chemical class. He believes that the intent of Chapter 258 is referring to therapeutically equivalent substitutes among the "same mechanism of action."

Dr. Feldman stated we should provide an algorithm to guide the use of the formulary.

Dr. Lemay wanted to reiterate how important it is for this to be a smooth process and we need to keep communication open with insurer partners to ensure access.

3. DISCUSSION OF EVALUATION CRITERIA

Interim Director Sheehan started the next agenda item but stating that it was important that we work to finalize the evaluation criteria so we can begin to use it in the evaluation of drug products. We will revisit comments and discussion from previous meetings and the expert feedback received on October 1. The Department has taken all of this feedback and developed draft criteria for your consideration.

Interim Director Sheehan introduced Associate Executive Director Dunn to facilitate conversation on the evaluation criteria, starting with the heightened public health risk criteria.

Associate Executive Director Dunn stated at our September 8th meeting, there was discussion and momentum to classify all drugs that have already been designated by the DEA as Schedule II and Schedule III as having a heightened public health risk. He added the DEA definition of Schedule II includes the drug having a high potential for abuse and is considered dangerous. He stated Schedule III drugs are defined as having a moderate to low potential for dependence.

From this information and previous conversation on the topic, Associate Executive Director Dunn asked if the Drug Formulary Commission wants to place all Schedule II and III drug groups on the formulary as having a heightened public health risk.

Interim Director Sheehan thanked you Mr. Dunn for providing this overview. Interim Director Sheehan clarified that should the Commission decide to place all of the Schedule II and III groups on the formulary as having a heightened public health risk, this decision becomes an inclusionary decision. He added this would mean that all of the drug products in each individual drug group would also be considered a heightened public health risk. Interim Director Sheehan states this would include 333 individual drug products in all of the Schedule II groups and 48 individual drug products in all of the Schedule III groups.

Interim Director Sheehan stated should the DFC decide not to place all of the Schedule II and II groups on the formulary as having a heightened public health risk, it would require review, analysis and vote on each individual drug within each drug group. These actions make this decision an exclusionary decision. With this decision, 333 individual drugs products would have to be reviewed in all Schedule II drug groups and 48 individual drug products would have to be reviewed in all Schedule III drug groups.

He further stated that we will have a review process to determine if drugs are appropriate therapeutically equivalent substitutes to include on the formulary but it will be different than determining if a drug has a heightened public health risk. This will be discussed later today. We have presented this question to the Commission based on the conversation among the members at our September 8th meeting, which indicated a likelihood of consensus to apply all the Schedule II and III drug groups to the formulary as having a heightened public health risk.

Interim Director Sheehan stated we also know that the DEA has already designated these drugs has having a public health risk component. He added we raise it today to try to determine if there is a consensus to take this action.

Ms. Steinberg stated Massachusetts General Law Chapter 94C includes how drugs are to be classified and that scheduling has taken into consideration the risk of abuse. I think that the legislative intent of Chapter 258 is for the Commission to identify a subset of these drugs that have a heightened public health risk.

Dr. Jeffrey suggested that if there won't ever be a therapeutically equivalent ADF substitute, then why put the drug on the formulary as having a heightened public health risk? Associate Executive Director Dunn stated that as a practical matter, there are some drugs that do not have a ADF today but including the drug on the formulary as having a heightened public health risk allows us to move the process forward and be ready for future advancements.

Dr. Brandoff asked how the vote on the drugs to include as having a heightened public health risk does more than the current scheduling of these drugs? Associate Executive Director Dunn noted that it allows this to be an inclusionary process versus an exclusionary process. Dr. Brandoff asked how the PMP data will be worked in and Mr. Dunn responded that it will be used as part of the draft monograph, which will be discussed later.

Mr. Feldman noted that things change so quickly, that everything should be included just to make sure that if it becomes an issue later, we will already have it on our radar. As substitutions become available, we will be able to look back at some of these drugs that were included as heightened, but did not have a substitute on the formulary. Interim Director Sheehan noted that the DEA already made the determination based on criteria and the decision to include all Schedule II and Schedule III drug groups on the formulary supports that. This will be a fluid process and we will be able to revisit the formulary and make future determinations. The goal is for this determination to allow us to move on and have a more expedient process based on the DEA's previous decisions.

Dr. Carr noted that the burden of proof is on us to determine if a drug does not have a heightened public health risk by definition. He supports an inclusive process.

Dr. Freedman is in support of including all of the Schedule II and Schedule III drug products but would suggest a more pragmatic approach would be to start with Schedule II drugs and complete Schedule III drugs later.

Mr. Feldman asked if this work ends and begins with opioids. Interim Director Sheehan noted that Chapter 258 indicates that our work is related to Schedule II and III opioids.

Dr. Brandoff stated that he is clear on what heightened public risk means for the Commission's purpose but that doesn't mean that a product will be taken off the market.

Interim Director Sheehan stated after hearing all your thoughts, I'd like to ask if there is motion to place all Schedule II and III opioids on the formulary as having a heightened public health risk. Dr. Freedman made the motion to include all Schedule II and III drug products on the formulary as having a heightened public health risk. This was seconded by Dr. Carr and the vote was unanimous.

Interim Director Sheehan called upon a break at 10:15 am, to resume the meeting at 10:25 am.

Following the break, Interim Director Sheehan indicated that Associate Executive Director Dunn will continue the presentation to bring us on to our next topic, establishing the criteria for the determination of therapeutically equivalent substitutes.

Associate Executive Director Dunn continued his presentation and went over the review process for determining if a drug should be placed on the formulary as being a therapeutically equivalent drug product. He discussed the need to use evidence-based decision making and reviewed literature and data elements to consider as part of the criteria to determine if a drug is a therapeutically equivalent substitute.

Associate Executive Director Dunn introduced the use of a monograph to apply this criteria to the evaluation of the drugs. He indicated that the monograph will be completed for each drug product, ensuring consistency and transparency. The draft monograph was displayed at the meeting and copies were provided to the Commission members in their binders.

Dr. Carr asked if we are only looking at different specific formulations? Associate Executive Director Dunn stated that is up to the Commission for discussion.

Mr. Feldman asked how data from the PMP will be part of review and decision making. Associate Executive Director Dunn indicated that PMP data has been requested by the Commission and will be used to look at decision-making. Mr. Feldman asked if the data will show, in the aggregate, what people are being prescribed. Associate Executive Director Dunn said yes. Mr. Mundy clarified the drugs that are reported to the PMP. Pain management drugs do go into the PMP but not doctor's orders for addiction management.

Mr. Feldman provided feedback on slide 26 and stated that we want to be specific on the data to include as we will want to know the efficacy measures and if the ADF has deterred. He also stated other edits for inclusion in the criteria.

Dr. Jeffrey noted that we want to look at popular websites that show people how to circumvent the ADFs.

Dr. Lemay suggested that clinical practice guidelines be included.

Dr. Carr stated that we should revisit the scope of the drug and look at other reviews such as the *Cochrane Review*. There should also be a phrase included to acknowledge individual variability.

Associate Executive Director Dunn then went into more detail on the draft monograph.

Dr. Freedman asked of all the 381 individual drug products within Schedule II and III, how many would meet the criteria for Section 2 of the draft monograph. Associate Director Dunn did not know.

Interim Director Sheehan sated that we wanted to start the discussion with you around the criteria in the monograph. As way of introduction, we wanted to identify ways to streamline the review process and prioritize drugs for your review.

Dr. Carr suggested that we think about this as a sensitivity analysis to provide evidence to make a determination.

Mr. Campbell asked if we were to get overdose data, if it can be worked into the threshold in the monograph for the criteria of prescriptions written and dosage units dispensed as we don't want to not review drugs that don't meet this criteria but are widely abused. Interim Director Sheehan responded stating that data requests from the Commission will start being presented in November.

Dr. Brandoff stated that he liked that the draft monograph is iterative and allows for consistency.

Dr. Freedman inquired which of the drugs would be greater than 250,000 prescriptions prescribed. Interim Director Sheehan stated Sections I and II of the draft monograph contain questions that when answered, may determine that the drug does not warrant further review at this time. Dr. Freedman also noted that if we use the two criteria in the monograph to start the evaluation, then only a handful of drug products will be fully evaluated. Associate Executive Director Dunn agreed and indicated that the application limits the universe of drugs that go through the entire monograph.

Mr. Feldman suggested adding overdose data to the preliminary review. Dr. Freedman responded stating that the cause of death may not be due to that drug even if it is in his/her system. Agree that it needs to be considered but not as a filtering question. Mr. Feldman also asked questions about the process of reviewing the monograph. Associate Executive Director Dunn noted that while the process hasn't been defined, you will get packets in advance. We summarize the information in the packets at the meetings and then discuss.

Dr. Brandoff asked about how differences of mechanics of application will be addressed. Associate Director Dunn indicated that for some, if they don't have an ADF, then they will not go through the entire review process at this time.

Dr. Carr noted that when designing a process like this, it is often helpful to bring in other end users/stakeholders. Would that be possible as we want to make sure we aren't leaving anything behind. Interim Director Sheehan asked the Commission to consider what this type of process may look like. We will take it into consideration so please send me your thoughts.

Dr. Doyle-Petrongolo asked if the monograph was just for the Commission or is a completed monograph meant to be for prescribers? Interim Director Sheehan stated that it is just for the Commission. Dr. Doyle-Petrongolo asked if questions 1 and 2 on the monograph both need to be answered "yes" to go on for further evaluation. Interim Director Sheehan stated that it was a decision point for the Commission. It was meant to help us prioritize the work and review of drug products.

Dr. Carr suggested adding an asterisk that implies that the monograph may change if other drugs come on the market.

Associate Executive Director Dunn will refine the monograph and bring back to the next meeting.

CLOSING REMARKS/ADJOURNMENT

Interim Director Sheehan thanked the Committee members for attending today's meeting. He stated we made a lot of progress today and will continue this work at our November 5th meeting. He acknowledged that it is possible that he will not be in attendance at the November 5th meeting. If so, Lindsey Tucker, Associate Commissioner at DPH, will chair the meeting. I look forward to seeing you at the meeting on November 19th. He added that Suzanne Cray will also be leaving for maternity leave in the upcoming weeks. Once Suzanne transitions out, Lauren Nelson, the Policy Director at the Bureau of Health Care Safety and Quality, will serve in this capacity. He stated, you will hear from Lauren regarding all meeting logistics and she will serve as a point of contact.

Interim Director Sheehan asked for a motion to adjourn. Dr. Carr motioned to adjourn, and Dr. Jeffrey seconded the motion. All members voted to adjourn. The meeting was adjourned at 11:52 AM.

LIST OF DOCUMENTS PRESENTED TO THE DRUG FORMULARY COMMISSION FOR THIS MEETING:

1. Docket of the meeting.
2. Copies of the October 1, 2015 draft minutes.
3. October 15, 2015 Meeting Presentation
4. October 15, 2015 Draft Monograph